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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,129	12/26/2001	Rajneesh Taneja	ABB1259P0072US (6762.US.0	3432

7590 03/21/2005

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,129	TANEJA ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination under 37 C.F.R. §1.114, the request for extension of time (3 months) and Applicant's Arguments/Remarks, all filed 11/10/04 is acknowledged.

Claims 1-29 are pending. Claims 1-29 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/04 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-11, 15-21, 23, 24 and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Phillips (US Pat. No. 6,489,346 B1) (hereafter 'Phillips I').

Phillips I ('346) discloses a method for treating acid-related gastrointestinal disorders comprising administering to a patient a non-enteric pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent, wherein the pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal (see Abstract; Claims); (col. 11, lines 36-44); (col. 13, line 47 – col. 14, line 26). At column 13, lines 47-53, Phillips disclose that mixtures of the buffering agents can be utilized. Suitable buffering agents disclosed include sodium bicarbonate, potassium bicarbonate, aluminum hydroxide/sodium bicarbonate co-precipitate and sodium carbonate (see col. 13, line 63 – col. 14, line 14); (col. 17, lines 58-60). Potassium carbonate is disclosed at column 22, lines 7-8. Sodium bicarbonate is provided in amounts of about 1000 mg to about 1680 mg (see claim 17). The non-enteric proton pump inhibitors include a substituted benzimidazole of lansoprazole or salts thereof (see Abstract). Example IV at column 22, lines 1-39 demonstrates an effervescent formulation whereby omeprazole powder was diluted with sodium bicarbonate, citric acid and potassium carbonate to form a homogeneous mixture of omeprazole powder.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8, 12-14, 22, 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US Pat. No. 5,840,737) (hereafter 'Phillips II') in view of Phillips (US Pat. No. 6,489,346 B1) (Phillips I).

Phillips II ('737) teaches a method for treating gastric acid disorders by administering to a patient a single dose of a pharmaceutical composition including an aqueous solution/suspension of proton pump inhibitors – omeprazole, lansoprazole or other substituted benzimidazoles and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal (see abstract and claims). Phillips also teaches a pharmaceutical composition, which includes omeprazole or other substituted

benzimidazoles and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal (see abstract and claims).

Phillips II teaches a method for treating gastric acid disorders wherein the Group IA metal is sodium and potassium (see claims 1-3).

It is stated that the pharmaceutical composition is prepared by mixing omeprazole or other substituted benzimidazoles and derivatives thereof with a solution including a bicarbonate salt of a Group IA metal. Preferably, omeprazole powder or granules are mixed with a sodium bicarbonate solution to achieve a desired final omeprazole concentration (col. 7, line 50 through col. 8, line 5).

Phillip II states that the pharmaceutically acceptable carrier includes the bicarbonate salt of the Group IA metal and can be prepared by mixing the bicarbonate salt of the Group IA metal, which is preferably sodium bicarbonate, with water. The concentration of the bicarbonate salt of the Group IA metal in the composition generally ranges from approximately 5.0% to about 60%. In a preferred embodiment, the preferred salt is sodium bicarbonate and is contained in a concentration of about 8.4% (col. 8, lines 6-17).

Suitable derivatives of omeprazole can be substituted for the omeprazole or other suitable substituted benzimidazoles, wherein these derivatives include lansoprazole (col. 8, lines 41-45).

The pharmaceutical composition can be used for the treatment of gastrointestinal conditions, including, active duodenal ulcers, gastric ulcers, gastroesophageal reflux disease (GERD), severe erosive esophagitis, poorly responsive systematic GERD, and pathological hypersecretory conditions (col. 8, lines 46-61).

The examples on columns 10-19 further demonstrate various embodiments of the invention in greater detail.

Additional agents that can be added include antimicrobial preservatives, antioxidants, chelating agents and buffers (column 9, lines 23-26).

Phillips II is deficient in the sense that he does not explicitly teach the instant ratios and amounts. However, in the absence of showing the criticality of the instantly claimed ratios and/or amounts, it is deemed obvious to one of ordinary skill in the art that suitable ratios and/or amounts could be determined through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters within the art. Moreover, the Examiner points out that generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unusual/unexpected results that accrue from the instant ratios or amounts.

Regarding the 'non-enteric' proton pump inhibitor claimed by Applicant, Phillips II teaches a method for treating gastric acid disorders whereby the use of enteric coatings can be used if desired, indicating that enteric coatings are optional. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to either employ enteric coatings if drug delivery in the intestines was desired or alternatively, to exclude enteric coatings if delivery of drug to the stomach was desired. The expected result would be a drug formulation having distinct rates of release.

Phillips II ('737) does not teach a *carbonate* salt of the Group IA metal.

Phillips I ('346) teaches a method for treating acid-related gastrointestinal disorders comprising administering to a patient a non-enteric pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent, wherein the pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and a *carbonate salt of a Group IA metal,* whereby suitable buffering agents include sodium carbonate, for example (see Abstract; Claims); (col. 11, lines 36-44); (col. 13, line 47 – col. 14, line 26).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the carbonate salt of the Group IA metal of Phillips I ('346) within the teachings of Phillips II ('737) who teaches bicarbonate salts of the Group IA metal because Phillips I explicitly teaches a proton pump inhibitor formulation comprising suitable buffering agents of both carbonates and bicarbonates of Group IA metals and teaches that the buffering agents (*i.e.*, carbonates/bicarbonates) function to substantially prevent or inhibit acid degradation of the proton pump inhibitor by elevating pH of the stomach sufficiently to achieve adequate bioavailability of the drug to effect therapeutic action. The expected result would be a non-enteric coated formulation wherein the bioavailability of the proton pump inhibitor is preserved to provide for the effective treatment and/or prevention of gastric acid related disorders.

Response to Arguments

Applicant's arguments filed 11/10/04 have been fully considered but were not found persuasive.

Firstly, Applicant argued that the 'Office Action contains the rejection of claims 1-29 under 35 U.S.C. §112, second paragraph and the rejection of claims 1-7, 9, 15-21 and 23 under 35 U.S.C. §102(b) over Phillips '737. Examiner points out that these rejections were withdrawn as stated in the Final Office Action filed 12/30/03 (see pg. 2).

Secondly, Applicant argued regarding the 35 U.S.C. 102(e) rejection of claims 1-7, 9-11, 15-21, 23 and 24 over Phillips I ('346) stating, "Phillips disclose the use of bicarbonate salts and do not disclose the use of *carbonate* salts in the formulations set forth therein. Phillips does not disclose the use of both carbonate and bicarbonate salts as required by the present claims".

These arguments have been thoroughly considered but were not found to be persuasive.

The prior art (Phillips I or '346) discloses compositions and methods for treating gastric acid disorders by the administration of a pharmaceutical composition comprising non-enterically coated proton pump inhibitors (i.e., omeprazole, lansoprazole, other substituted benzimidazoles) and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises bicarbonate salts and carbonate salts of a Group IA metal (see abstract and col. 13, line 47 – col. 14, line 26). The pharmaceutical composition can be used for the treatment of gastrointestinal conditions, including, active duodenal ulcers, gastric ulcers, gastroesophageal reflux disease (GERD), severe erosive esophagitis, poorly responsive systematic GERD, and pathological

hypersecretory conditions (col. 8, lines 46-61). Phillips ('346) teaches various buffering agents that include sodium *bicarbonate*, potassium bicarbonate and sodium *carbonate*, for example (see ref. col. 13, line 63 – col. 14, line 13). Additionally, Phillips I discloses at column 13, lines 47-53, that 'although sodium bicarbonate is the preferred buffering agent to protect the proton pump inhibitor (ppi) against acid degradation, many other weak and strong bases *and mixtures thereof* can be utilized (emphasis added). According to Phillips '346, buffering agents mean 'any pharmaceutically appropriate weak or strong base (and mixtures thereof)'. Examples of suitable buffering agents include both bicarbonates, such as sodium bicarbonate and also carbonates, such as sodium carbonate (see col. 13, line 65 and col. 14, line 5). Therefore, Phillips discloses the use of both carbonate and bicarbonate salts of the Group IA metal as claimed by Applicant. Thus, the reference of Phillips I '346 anticipates the claims.

Lastly, Applicant argued with respect to the Section 103(a) rejection stating, "Phillips ('346) does not disclose or suggest the use of both carbonate and bicarbonate salts as is presently claimed. Thus, there is no motivation for a skilled artisan to obtain the subject matter of claims 1-29 and the Section 103(a) rejection should be withdrawn."

Applicant's arguments have been considered, but were not found persuasive. Phillips ('737) is lacking only in the sense that he does not teach the carbonate salts of the Group IA metal from the Periodic Table of Elements. Phillips I ('346) remedies this deficiency of Phillips ('737) by teaching a proton pump inhibiting formulation comprising the incorporation of at least one buffering agent, wherein suitable buffering agents include carbonates, such as sodium carbonate and bicarbonates, such as sodium bicarbonate of the Group IA metal (see col. 13, line

47 – col. 14, line 5). Phillips '346 also teaches that mixtures of the buffering agents can be utilized (col. 13, lines 47-53). Ample motivation is provided by Phillips I ('346) to include both carbonate and bicarbonate salts because Phillips I teaches that the buffering agents (*i.e.*, carbonates/bicarbonates) function to substantially prevent or inhibit acid degradation of the proton pump inhibitor by elevating pH of the stomach sufficiently to achieve adequate bioavailability of the drug to effect therapeutic action. Therefore, a *prima facie* case of obviousness has been established since the prior art provides ample motivation to incorporate the same ingredients, such as carbonates and bicarbonates for effectively treating gastric acid disorders. The prior art teaches a proton pump inhibiting formulation comprising the same ingredients for the same field of endeavor, which is the treatment and/or prevention of gastric acid related disorders. Hence, in view of the above-delineated teachings of the prior art, the instant invention remains anticipated, obvious and unpatentable over the prior art of record.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H. N. Sheikh

Patent Examiner

Art Unit 1615

March 16, 2005